

DNA Procedures for Administering Proficiency Tests

1 Purpose

Proficiency testing is used to monitor the performance of qualified Examiners and Biologists who conduct mitochondrial DNA, nuclear DNA, and/or serology casework examinations, and/or DNA database sample processing for the FBI Laboratory DNA Units. The DNA Units include the DNA Casework Unit (DCU), the DNA Support Unit (DSU), the Federal DNA Database Unit (FDDU), and the Biometrics Analysis Unit (BAU) DNA group. Proficiency testing also demonstrates that the analytical procedures are being performed properly and produce results within established performance criteria.

2 Scope

2.1 These procedures apply to:

- DNA personnel who conduct examinations on evidence and/or database samples, interpret serology and/or DNA results, and/or perform technical reviews of casework and/or database analysis.
- DNA personnel who perform duties relating to the management, records, and tracking of proficiency tests and associated corrective actions.

2.2 DNA personnel are proficiency tested to the full extent in which they participate in casework and/or DNA database analysis in the following biology discipline categories of testing.

- 3.1 Nuclear DNA (twice per calendar year)
- 3.2 Mitochondrial DNA (twice per calendar year)
- 3.3 Body Fluid Identification (once per calendar year)
- 3.4 Individual Characteristic Database (twice per calendar year)

Proficiency testing, as applicable, will occur at the minimum frequency listed. Multiple categories of testing may be conducted on a single proficiency test.

2.3 Only external proficiency tests approved by ASCLD/LAB or from providers accredited to the International Standards for proficiency testing (i.e., ISO/IEC 17043) will be used to fulfill the requirements of the *Quality Assurance Standards for Forensic DNA Testing Laboratories* and *Quality Assurance Standards for DNA Databasing Laboratories* (together referred to as QAS).

2.4 For these procedures, an Examiner will include individuals (however titled) who perform the role of analyst (i.e., interpret data) and/or technical reviewer as defined by the QAS and a Biologist will include individuals (however titled) who perform the role of technician (i.e., perform examinations) as defined by the QAS and FBI *Laboratory Operations Manual* (LOM).

2.5 Laboratory support personnel whose responsibilities are limited to evidence management, sample collection, accessioning, and/or other lab duties exclusive of analytical techniques on forensic or database samples will not be proficiency tested.

3 Responsibilities

DNA personnel will follow the responsibilities identified in the appropriate LOM practices and those identified below.

3.1 The Technical Leader (TL) will:

- Review and approve the proficiency testing program described in this procedure.
- Review and approve the proficiency tests to be used in the DNA Units as required by the appropriate LOM practices.
- Ensure that all qualified Examiners and Biologists participate in proficiency testing to the full extent in which they perform casework analysis or DNA database sample processing.
- Review reported inconclusive or not interpretable results for compliance with DNA procedures.
- Evaluate all discrepancies and errors associated with a proficiency test and address the nonconformity, as necessary.
- Inform the appropriate CODIS Administrator of all non-administrative discrepancies that affect the DNA typing results and/or conclusions.
- Designate personnel other than Examiners and Biologists (i.e., contractors) to be proficiency tested.

3.2 The DNA Support Unit (DSU) Quality Assurance (QA) group will:

- Manage the DNA proficiency testing program to ensure compliance with these procedures.
- Ensure the responsibilities of the Unit Proficiency Test Representative listed in the appropriate LOM practices are fulfilled.
- Notify the TL of any serious problems or atypical results, discrepancies, and/or errors with a proficiency test distribution.
- Ensure that proficiency test results are submitted to the provider by the established due date.
- Ensure all participants are notified of their final test results.
- Ensure the TL is informed of the evaluation results of all participants.

3.3 Examiners will:

- Complete all proficiency tests assigned to them to the full extent in which they participate in casework or DNA database sample processing.
- Notify the TL if problems are encountered with the proficiency test samples which may negatively impact the successful completion of the test.
- Perform technical reviews and/or submit their proficiency test(s) for technical review.
- Perform reviews when not participating in the same distribution or after

completing his/her portion of a test in the same distribution.

- Return the completed proficiency test to the DSU QA Group by the established due date.

3.4 Biologists will:

- Complete all proficiency tests assigned to them to the full extent in which they participate in casework or DNA database sample processing.
- Complete the proficiency test in sufficient time to allow the Examiner to conduct his/her portion of the test.
- Notify the Examiner if problems are encountered with the proficiency test samples which may negatively impact the successful completion of the test.

4 Procedures

DNA personnel will comply with the FBI Laboratory *Quality Assurance Manual* (QAM) and the appropriate LOM practices, as well as the QAS requirements.

4.1 Serology Proficiency Tests

4.1.1 Examiners and Biologists that currently perform, interpret, and/or technically review serological casework examinations will participate in a minimum of one open, external serology proficiency test per calendar year (January through December).

4.1.2 Serology proficiency testing will be conducted in a manner consistent with typical casework and will involve the examination of potential biological materials for the presence or absence of blood and semen. The relevant tests routinely performed should be conducted on the items contained in the proficiency test.

4.1.2.1 The relevant tests will be determined using the case scenario provided by the PT provider for the test. If insufficient information is provided to make an informed decision, samples will be tested for both blood and semen.

4.1.2.2 Presumptive tests and confirmatory tests will be conducted as they would be in casework examinations. All possible serology tests need not be performed on each sample, as appropriate.

4.2 DNA Proficiency Tests

4.2.1 Examiners and Biologists that currently perform, interpret, and/or technically review DNA casework or database examinations will participate in a minimum of two open, external DNA proficiency tests per calendar year (January through December) in each applicable DNA technology (i.e., STR, Y-STR, mtDNA) in which they perform casework or database sample examinations.

4.2.1.1 Multiple technologies/categories of testing may be performed on a single proficiency test.

4.2.1.2 Participation in DNA proficiency testing is required between January 1st and June 30th and July 1st and December 31st of each year. The interval between the issuance of each test must be at least four months and no more than eight months.

4.2.1.3 If an individual is not administered a proficiency test and falls out of the proficiency testing cycle for a specific technology or methodology, that individual will not perform casework or databasing examinations using that technology or methodology until a requalification test is successfully administered. Refer to the section on Requalification Testing.

4.2.2 The methods and typing test kits used on proficiency tests in the calendar year will be in accordance with the QAS and in a manner consistent with typical casework or databasing applications.

4.3 The distribution date will be used to track the proficiency testing cycles. The DSU QA Group will maintain the proficiency testing schedule for DNA personnel.

4.4 DNA personnel will follow the reporting procedures established by the specific test provider. The comments section(s) of the test provider's results forms will be used to address any results or conclusions that fall outside the reporting restrictions of the test provider's results forms.

4.5 All proficiency tests will undergo the appropriate technical and administrative reviews in accordance with the appropriate LOM practices and DNA procedures prior to submission of the test results. Record of the technical and administrative reviews will be retained with the proficiency test records.

4.5.1 Data quality reviews (e.g., review of capillary electrophoresis (CE) data for determining need for reinjections) are not considered a confirmation of identification or a technical review of the proficiency test and therefore may be conducted by an individual participating in the same distribution.

4.5.2 Data confirmations conducted for technical review purposes (i.e., mtDNA sequence confirmations, FDDU secondary analysis review) will be conducted by an individual not participating in the same distribution or a participant who has completed his/her portion of the test.

4.5.3 Technical and administrative reviews of casework tests will be performed in accordance with the applicable DNA procedures for case file reviews.

4.5.4 Technical and administrative reviews of DNA databasing tests will be conducted as described below.

4.5.4.1 A secondary review (technical review) of the data will be performed and recorded in

Sample Tracking and Control Software (STACS). The secondary review may include the use of a National DNA Indexing System (NDIS) approved expert system. A secondary review of the data will include the following:

- A review of all DNA types to verify that they are supported by the raw or analyzed data
- A review of all controls, internal lane standards, and allelic ladders to verify that the expected results were obtained.
- A review to confirm that the reworked samples have appropriate controls

4.5.4.2 A technical review of all notes, worksheets, and electronic data supporting the results will be conducted and recorded in the proficiency test records.

4.5.4.3 An administrative review of the proficiency test records will be recorded in the proficiency test records.

4.6 Proficiency test results will be submitted to the proficiency test provider on or before the provider's due date.

4.6.1 The Proficiency Test Program Manager (PTPM) or the DSU QA group will submit test results for the individual test participants, unless a provider requires a participant submit their individual test results.

4.6.2 External tests not accepted by the provider do not satisfy the proficiency test requirement. If this should occur, a new external proficiency test will be ordered as soon as possible and appropriate records will be maintained.

4.7 Any potential inconsistency or error, or any issue with a proficiency test that may have affected the results or evaluation of the test should be proactively communicated to the Biology Proficiency Review Committee (PRC) through the PTPM.

4.8 Evaluation of Proficiency Test Results

4.8.1 All proficiency test results will be evaluated in accordance with the appropriate LOM practices and the QAS requirements. The *Proficiency Test Evaluation Form* (Appendix A) will be used to record the evaluation.

4.8.2 Results reported as inconclusive or not interpretable will be reviewed by the TL for compliance with unit specific procedures. This review may be conducted prior to the evaluation (i.e., as part of the administrative review).

4.8.3 The DSU QA Program Manager or designee will ensure that the completed *Proficiency Test Evaluation Form* (Appendix A) is provided to proficiency test participants in accordance with the appropriate LOM practice.

4.8.4 The TL will be informed of the results of all participants.

4.8.5 Proficiency test records will be maintained by the DSU QA Group.

4.9 Discrepancies and Errors

4.9.1 All discrepancies and potential technical, analytical, and/or administrative errors will be evaluated by the TL and/or the appropriate Unit Chief(s) and handled in accordance with the appropriate LOM practices. The TL will initiate necessary actions in conjunction with the Unit Chief(s).

4.9.2 The TL will inform the appropriate CODIS Administrator of all non-administrative discrepancies that affect the DNA typing results and/or conclusions at the time of discovery.

4.9.3 The DSU QA Group will ensure any corrected data sheets and exam sheets or DNA database notes are maintained with the appropriate proficiency test records.

4.10 Requalification Testing

4.10.1 When an individual is on extended leave (i.e., for a period that takes the individual out of the proficiency testing cycle), the TL will ensure that the individual completes any necessary training and completes a requalification test prior to resuming casework or DNA databasing examinations.

4.10.1.1 Individuals returning from leave of greater than 2 months will be given a reacclimation period prior to requiring an external proficiency test or requalification test be completed.

4.10.1.2 An external proficiency test may be used as a requalification test provided that the results of the external proficiency test are received from the manufacturer and consequently evaluated as successful prior to the individual being requalified to perform independent casework or DNA databasing examinations.

4.10.2 External proficiency tests or test samples that are not consumed during the corresponding test period (e.g., evidence type samples from a database test, semen samples from a mtDNA test) will be retained and may be used for requalification testing, competency testing, or for other internal testing.

4.10.2.1 When an unused external proficiency test is used as a requalification test it will be administered as an internal test according to the appropriate LOM practices.

4.10.3 The *Proficiency Test Evaluation Form* (Appendix A) will be utilized to record the evaluation of an internal test.

4.10.3.1 This form is not required for competency testing administered following the completion of training.

5 Records

5.1 A member of the DSU QA Group will ensure the following information is recorded for all external proficiency tests administered in the DNA Units and that the information is available upon request.

- Name(s) of test participant(s).
- Test type (position type and internal/external).
- Test identification number.
- Distribution date.
- Date returned.
- Due date.
- Evaluation date.
- Name of evaluator.
- Results: satisfactory or unsatisfactory.
- Description of discrepancy, when appropriate.

5.2 A member of the DSU QA Group, or a designee, will ensure the appropriate records as listed in the LOM are retained in a hardcopy or electronic format.

6 References

FBI Laboratory Quality Assurance Manual

FBI Laboratory Operations Manual

DNA Procedures Manual

Federal Bureau of Investigation, Quality Assurance Standards for Forensic DNA Testing Laboratories, latest revision.

Federal Bureau of Investigation, Quality Assurance Standards Audit for Forensic DNA Testing Laboratories, latest revision.

Federal Bureau of Investigation, Quality Assurance Standards for DNA Databasing Laboratories, latest revision.

Federal Bureau of Investigation, Quality Assurance Standards Audit for DNA Databasing Laboratories, latest revision.

Rev. #	Issue Date	History
8	05/25/16	<p>Changed DCU/FDDU to DNA personnel and added BAU.</p> <p>2.3 Added allowance for accredited provider.</p> <p>2.5 Added lab support personnel will not be tested.</p> <p>3.2 Added “or designee” and fulfills responsibilities of unit PT rep.</p> <p>4.2.1.3 Added reference to Requalification Test section.</p> <p>4.3 Reworded only. Distribution date still used to track PT cycles.</p> <p>4.6.1 Added allowance for participant to submit a test.</p> <p>4.10 Changed to Requalification Tests and reordered requirements.</p> <p>4.10.1.1 Added reacclimation period.</p> <p>4.10.1.2 Added that an external PT may be used as a requal test.</p> <p>5 Added “or designee”</p> <p>Appendix B Changed Report of Exam to Lab Report.</p>
9	06/01/17	<p>Revisions to align with LOM revision on 12/15/16</p> <p>1 Added qualified and defined DNA Units</p> <p>2.2 Deleted ASCLD/LAB-International replaced with biology discipline</p> <p>3.1 Added responsibility to approve tests</p> <p>3.2 Removed designee</p> <p>3.3 Added reviewer requirement</p> <p>4.1.2.1 and .2 Added context to the term relevant tests</p> <p>4.5.1 moved the FDDU secondary review example to 4.5.2</p> <p>4.5.3-4.5.4.3 Added review instructions and procedures for FDDU reviews</p> <p>4.9.3 Added maintaining corrected records</p> <p>4.10.3 and Appendix B Deleted Proficiency Test Results Form</p> <p>5.1 Replaced PT database with information that must be maintained</p> <p>Appendix A Revised form to list participants with signatures</p>

Approval

Redacted - Signatures on File

Appendix A: *DNA Proficiency Test Evaluation Form*

Redacted - Form on File